

United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

mm [Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]
1-75
DRUGS AND DEVICES¹

The cases reported herewith were instituted in the United States District courts by the United States attorneys, acting upon reports submitted by direction of the Secretary of Agriculture.

GROVER B. HILL, *Acting Secretary of Agriculture.*

WASHINGTON, D. C., March 16, 1940.

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MISBRANDED DRUGS AND DEVICES

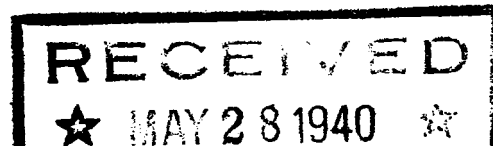
HEADACHE REMEDIES, PAIN RELIEVERS, AND SEDATIVES

- 1. Misbranding of B. C. Headache Powders. U. S. v. 46 Dozen Packages of B. C. Default decree of condemnation and destruction. (F. D. C. No. 111. Sample No. 25097-D.)**

These powders consisted essentially of acetanilid, aspirin, caffeine, and potassium bromide. They would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, which directed a dosage of one powder which might be repeated once or twice at intervals of 3 or 4 hours if indicated. Its labeling failed to reveal facts material with respect to the consequences which might result from the use of the article under the conditions of use prescribed in the labeling and failed to bear warnings against use in pathological conditions where its use might be dangerous to health or against unsafe dosage or duration of administration.

On or about January 4, 1939, the United States attorney for the Northern District of Georgia filed a libel against 46 dozen packages of B. C. Headache Powders at Atlanta, Ga.; alleging that the article had been shipped in interstate commerce on or about November 30, 1938, by B. C. Remedy Co. from Durham, N. C.; and charging that it was misbranded for the reasons appearing above.

¹ Notices of Judgment under the Federal Food, Drug, and Cosmetic Act are published in three series: Foods (F. N. J.); Drugs and Devices (D. D. N. J.); and Cosmetics (C. N. J.).



see JRW

On March 16, 1939, the B. C. Remedy Co., claimant, having petitioned that it be permitted to withdraw its claim and answer, such petition having been granted, and no answer or defense being before the court at that time, judgment of condemnation was entered and the product was ordered destroyed.

2. Misbranding of Stanback Headache Powders. U. S. v. 309 Dozen Packages of Stanback Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 207. Sample Nos. 44801-D, 44863-D.)

These powders contained acetanilid, potassium bromide, aspirin, caffeine, and a trace of sodium bicarbonate. They would be dangerous to health when used in the dosage or with the frequency prescribed, recommended, or suggested in the labeling, which bore directions that one powder be taken for relief of the discomfort of simple headache and neuralgia, and muscular aches and pains, and that another powder might be taken in 30 minutes if necessary; that one powder be taken as a sedative, to be repeated in 2 or 3 hours if necessary, and that one powder be taken at the first sign of a cold and one 2 hours later for relief of the discomfort of simple head colds; and stated that one powder at night just before retiring was especially recommended for such head colds. Its labeling failed to reveal facts material with respect to the consequences which might result from its use under the conditions of use prescribed in the labeling and failed to bear warnings against use in those pathological conditions in which its use might be dangerous to health, or against unsafe dosage or duration of administration.

On March 23, 1939, the United States attorney for the Northern District of Georgia filed a libel against 309 dozen packages of Stanback Headache Powders at Atlanta, Ga., alleging that the article had been shipped in interstate commerce within the period from on or about January 12 to on or about March 8, 1939, by the Stanback Co. from Salisbury, N. C.; and charging that it was misbranded for the reasons appearing hereinbefore.

On April 15, 1939, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

3. Misbranding of Goody's Headache Powder. U. S. v. 1,524 Envelopes of Goody's Headache Powder. Default decree of condemnation and destruction. (F. D. C. No. 211. Sample No. 45525-D.)

These powders contained potassium bromide, acetanilid, aspirin, and caffeine. They would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, which directed that for headaches and neuralgia one powder be taken, and repeated in 2 hours if necessary, with succeeding doses in 3 or 4 hours if necessary; that for muscular aches and pains one powder be taken and repeated in 3 or 4 hours as required; that as a sedative for discomfort of headaches due to automobile and train travel, one powder be taken and repeated in 2 hours if necessary; that for simple head colds and for reducing simple fever one powder be taken as soon as symptoms appear, to be repeated in 3 or 4 hours if required. Its labeling also failed to reveal facts material in the light of the said directions and similar representations on the envelope, and failed to reveal facts material with respect to consequences which might result from use of the article under the conditions of use prescribed in the labeling, and failed to bear adequate warnings against use of the article in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users.

On April 4, 1939, the United States attorney for the Eastern District of South Carolina filed a libel against 1,524 envelopes of Goody's Headache Powder at Columbia, S. C.; alleging that the article had been shipped in interstate commerce on or about March 1, 1939, by Goody's, Inc., from Winston-Salem, N. C.; and charging that it was misbranded for the reasons appearing above.

On May 24, 1939, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

4. Misbranding of B-B Headache Powders. U. S. v. 596 Envelopes of B-B. Default decree of condemnation and destruction. (F. D. C. No. 215. Sample No. 45524-D.)

These powders contained potassium bromide, acetanilid, aspirin, and caffeine. They were recommended in the labeling as a quick relief of pain and discomfort due to muscular aches, head colds, simple headaches, simple neuralgias, periodic